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Environmental interventions for preventing falls in older people living in the community (Protocol)

Clemson L, Stark S, Pighills AC, Torgerson DJ, Sherrington C, Lamb SE

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[Intervention Protocol]

Environmental interventions for preventing falls in older people living in the community

Lindy Clemson[1], Susan Stark[2], Alison C Pighills[3], David J Torgerson[4], Catherine Sherrington[5], Sarah E Lamb[6]

[1]Faculty of Health Sciences, The University of Sydney, Lidcombe, Australia. [2]Participation, Environment and Performance Laboratory, Program in Occupational Therapy, Washington University, St Louis, MO, USA. [3]Mackay Institute of Research and Innovation, Queensland Health and Division of Tropical Health and Medicine, James Cook University, Mackay, Australia. [4]Department of Health Sciences, University of York, York, UK. [5]Institute for Musculoskeletal Health, School of Public Health, Faculty of Medicine and Health, The University of Sydney, Sydney, Australia. [6]Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford, Oxford, UK

Contact address: Lindy Clemson, Faculty of Health Sciences, The University of Sydney, East St. Lidcombe, Lidcombe, NSW, 1825, Australia. lindy.clemson@sydney.edu.au.

A B S T R A C T

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To assess the effects (benefits and harms) of environmental interventions (such as assistive devices, and reduction of fall hazards in home, outdoors, and public places) for preventing falls in older people living in the community.

B A C K G R O U N D

The environmental interventions tested in this review are those aimed at reducing the risk of falls of older people living in the community from the interaction with their physical environment, whether indoors or outdoors. These may be single interventions, such as non-slip walking shoes or assistive devices, or more complex interventions, such as adaptations of the home environment to reduce falls risk combined with education on fall hazards following a fall-risk assessment of the home environment.

Description of the condition

Falls and fall-related injuries are common and can have serious consequences for older people. About a third of community-dwelling people over 65 years of age fall each year (Campbell 1990; Tinetti 1988), and the rate of fall-related injuries increases with age (Peel 2002). Around 10% of falls result in a fracture (Campbell 1990; Tinetti 1988); fall-associated fractures in older people are a significant source of morbidity and mortality, Scuffham 2003, and are an independent predictor of admission to a nursing home (Gaugler 2007). Most fall-related injuries are minor, such as bruising, abrasions, lacerations, strains, and sprains, but they are still associated with pain and reduced function and can negatively affect quality of life.

Fear of falling and loss of confidence can result in other conse-

quences including self restricted activity levels. This can impact on strength and balance, contributing to frailty where the person does not have physical reserves, and leading to a reduction in social interactions (Jorstad 2005). Both injurious and non-injurious falls can have these psychological and subsequent physical effects.

Epidemiological studies of varying quality have identified a number of risk factors for falling in community-dwelling older people (Deandrea 2010; Lusardi 2017). These risk characteristics can be broadly classified as medical, mobility, sensory, psychological, medication-related, environmental, or behavioural. Environmental fall-related risks include environmental factors such as slippery or uneven surfaces, clutter, poor lighting, poor footwear, step hazards, unsafe rails, and loose mats (Clemson 1999; Stevens 2014; Todd 2007). Behavioural fall-related risk factors include, for example, rushing, not paying attention to the path ahead, or poor ladder/climbing safety (Clemson 2003; Peel 2000). Other fall-related risk factors include increasing age, previous falls, walking aid use, gait problems, difficulty with activities of daily living, slower gait speeds, dizziness, fear of falling, urge incontinence, comorbidity, vision impairment, chronic diseases such as Parkinson's disease, depression, and dementia, and history of stroke. These factors can modify the way a person negotiates their physical environment. It is estimated that 60% of falls have multiple causal factors, Campbell 2006, and that more than 30% are attributed to environmental causes alone (Rubenstein 2006). Multiple contributing and interacting factors include, for example, slower gait, poor vision, and tripping on a loose mat resulting in a fall.

Interventions have largely been conducted in higher-income countries, and there is a lack of research on how translatable these interventions are cross-culturally where environments can differ greatly (Hill 2018; Shi 2014; Stewart 2015). This is particularly so for low-income countries, where the determinants and conditions associated with fall-related injuries are complex and poorly understood (e.g. narrow steps with poor lighting or the water source being outside the home).

Despite early attempts to achieve a consensus definition of 'a fall' (Anonymous 1987), many definitions still exist in the literature. It is particularly important to have a clear, simple definition for studies in which older people record their own falls, as their concept of a fall may differ from that of researchers or healthcare professionals (Zecevic 2006). A consensus statement defines a fall as "an unexpected event in which the participant comes to rest on the ground, floor, or lower level" (Lamb 2005). The recommended wording when asking study participants is: 'In the past month, have you had any fall including a slip or trip in which you lost your balance and landed on the floor or ground or lower level?' (Lamb 2005).

Description of the intervention

Environmental approaches are aimed at improving individual safety at home, outdoors, and in community and public places to re-duce the risk of falls in older people living in the community. This may include assessment for and the provision of an assistive device (see examples below), material adaptations (e.g. clearing pathways, fastening carpets, non-slip strips on step edges), behavioural adaptations (e.g. avoiding ladder use) or structural modifications (e.g. installing a skylight to improve visibility) (Clemson 1997; Gitlin 2009; Peel 2000; Stevens 2014).

The intervention descriptors are based on the Prevention of Falls Network Europe (ProFaNE) taxonomy (Lamb 2005; Lamb 2007), with refinement of descriptors to capture emerging literature over the last 10 years. We will cover the following four categories of environmental interventions in this review. Please note that the description of 'home', which can be indoors or outdoors, reflects the primary location of the intervention but does not exclude extension to public places.

1. Assistive technology as a single or stand-alone intervention to reduce falls.
2. Information/education on environmental fall risks as a stand-alone intervention to reduce falls.
3. Home modifications as a single or stand-alone intervention that aims to remove barriers to function and improve task performance.
4. Home fall hazard reduction intervention as a single- or multiple-strategy intervention. This is a package of strategies that aims to reduce falls.

The following is a description of these interventions. A table showing the links to the ProFaNE fall prevention taxonomy and further examples can be found in Appendix 1.

1. Assistive technology refers to devices, equipment, products, or systems that support a person to increase or maintain their ability to perform a task or increases the ease and/or safety with which a task can be performed (WHO 2004). The aim for fall prevention is on safe performance of mobility or tasks. Examples of single-strategy assistive technologies for fall prevention include personal mobility devices (e.g. walking aids); body-worn aids (e.g. antislip devices for shoes, orthotic footwear); communication and sensory (e.g. eyeglasses, hearing aids); protection (e.g. alarm sensors and systems); and self care aids (e.g. grab bars or other self care aids as a sole intervention). These interventions typically include information/education on reducing risk of falls specific to the intervention.

2. Information/education about reducing environmental fall risks in the home as a stand-alone intervention. While often provided within an intervention, if given as a single environmental approach, information/education involves providing generalised information about environmental fall risks or self assessment home audits associated with environmental hazards and no active intervention (Horowitz 2013). The intervention can be delivered in various ways, such as booklets and other written materials, videos, lectures, and checklists including via mobile apps.

3. Home modifications to improve task performance,

accessibility, and independence. This stand-alone intervention makes changes and adaptations to the permanent physical features of the home to meet the needs of people with activity limitations to performing daily living activities so that they can continue to live independently (Tanner 2008). The aim of these home visits is to remove barriers to function, enable ease of task performance, improve accessibility, and reduce accidents (Fange 2005; Tanner 2008). The focus is primarily to improve task performance and independence of individuals with functional impairments or to reduce the demands on carers (Gitlin 2009). Home modification interventions differ from a fall hazard reduction intervention, which focuses primarily on fall prevention (Peterson 2008; Pighills 2016). Studies that include any component that is considered a fall hazard assessment or that includes specific fall hazard management strategies to reduce falls would be included in category 4 as a 'package of strategies'.

4. Home fall-hazard reduction: environmental assessment, adaptation, and modification to reduce fall hazards in and about the home or outdoors, or both. This intervention category may include any of the following: assessment of fall hazards, awareness raising of fall risks within the person's environment, joint problem solving, environmental adaptations, relevant assistive technologies, and environmental and behavioural safety strategies to reduce fall risk (Clemson 1997; Iwarsson 2009; Peterson 2008; Pighills 2016). Although the environmental intervention is oriented towards the home, the outdoors, or both venues, extension to public places is possible. The focus of this intervention is on fall prevention, and solutions focus primarily on safety adaptations rather than on major structural changes. Criteria have been developed to determine the intensity of such interventions; these include "(a) a comprehensive evaluation process of environmental hazard identification and priority setting taking into account both personal risk, individual capacity and assessment of the person's environment, (b) the use of an assessment tool validated for the broad range of potential fall hazards, (c) inclusion of formal or observational evaluation of the functional capacity (physical capacity, behaviour, functional vision, habits) of the person within the context of their environment, and, (d) the provision of adequate follow-up by the health professional and support for adaptations and modifications", and (e) the active involvement of the older person in the assessment and priority setting of fall hazards (Clemson 2008).

Environmental interventions are delivered by various individuals, ranging from health professionals (occupational therapists, ergotherapists, and nurses) to healthcare workers (care or support workers without a professional qualification). They can be conducted as part of a consultation (e.g. aids or education provided in hospital), telerehabilitation (e.g. Sanford 2004), or, more often, conducted via a home visit.

This review will consider all types of environmental interventions and all delivery modalities.

Environmental interventions can be delivered as part of a multi-component intervention (e.g. along with exercise or medication review). The impact of such programmes is investigated in a separate Cochrane Review (Hopewell 2016).

How the intervention might work

The quality, intensity, and consequent outcomes of environmental assessment and intervention have been conceptualised in terms of person-environment fit models (Gitlin 2003; Pighills 2016). Law's Person, Environment, Occupation (PEO) model proposes that it is the interaction and fit between the person's capacity (e.g. strength, vision), their environment (e.g. the layout), and the occupation (e.g. task or activity) that is important, and when one of these three elements is affected or altered then this impacts on the others (Law 1997). Competence-environmental press models elaborate further on the relationship between the person's competencies and the demand placed on the individual by the physical environment (Nahemow 2000). These models support the idea that the person's capacity and their task performance should be assessed and considered when determining environmental solutions. Observational studies show that the mere presence of a hazard is not associated with falling (Lord 2006); rather it is the interaction between capacity, environmental barriers, and tasks that results in falls. This further supports the relevance of assessment of all three elements to reduce fall risk.

Environmental interventions are likely to modify risk by adapting or changing the environment, removing fall hazards, or providing an assistive device to afford protection from risk of falling; by enabling people to mobilise and engage in activity in a safer way; by compensating for specific risk factors known to be predictive of falls (such as age-related changes to motor and sensory systems, gait or vision impairment, cognitive impairment, and impairment or limitations related to chronic illness); by modifying risky behaviours; or by avoidance of hazardous situations. Alternatively, some interventions (new glasses, non-slip modifications to outdoor shoes) might increase outdoor activity and exposure to risk and increase falls. Home modification interventions that primarily aim to improve independence, task performance, and function may not include a sufficient focus on fall prevention.

Why it is important to do this review

This review covers a key set of interventions arising from the splitting of the scope of Gillespie 2012, which covered all interventions. Gillespie 2012 concluded that "Home safety interventions reduce rate of falls and risk of falling" and that an "anti-slip shoe device for icy conditions significantly reduced winter outside falls in one study". Gillespie 2012 found several studies that tested other assistive devices as single interventions, with mixed reports of effectiveness.

An update of the effects of environmental interventions is warranted given that evidence is emerging and new trials have been published. With projected demographic changes and people living longer (He 2016), the number of older people at risk for falls living in the community is increasing, which will magnify the consequences associated with falls and fall-related injuries to both the individual and to society.

Different environmental intervention types, different delivery approaches, or for whom, may have different effects on falls and fall-related injuries, so careful analysis of the impact of these differences is crucial. This evidence is important for healthcare professionals, policymakers, consumers, researchers, and others with an interest in this topic. The formal evaluation of cost-effectiveness, cost benefit, or cost utilisation of environmental interventions for falls prevention is also important for making informed decisions about application.

OBJECTIVES

To assess the effects (benefits and harms) of environmental interventions (such as assistive devices, and reduction of fall hazards in home, outdoors, and public places) for preventing falls in older people living in the community.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials, either individual or cluster randomised, that evaluate the effects of environmental interventions on the incidence of falls in older people living in the community. We will exclude quasi-randomised trials (e.g. allocation to groups by alternation or date of birth).

Types of participants

We will include trials if they specify an inclusion criterion of 60 years of age or over. We will include trials involving younger participants if the mean age minus one standard deviation (SD) is greater than 60 years. We propose to include trials where the majority of participants were living in the community, either at home or in places of residence that, on the whole, do not provide residential health-related care or rehabilitative services, for example hostels (in Australia), retirement villages, or sheltered housing. Trials with mixed populations (community and higher-dependency places of residence) will be eligible for inclusion if data are provided for

subgroups based on setting, or the numbers in higher-dependency residences are very few and balanced in the comparison groups. We will include trials recruiting participants in hospital if the majority were discharged to the community and this is where most of the intervention was delivered and falls were recorded, or where the in-hospital intervention or consultation is aimed at providing advice or education about home hazards postdischarge (and not about fall prevention in-hospital).

We will exclude studies that test interventions for preventing falls in people after stroke and with Parkinson's disease, as these topic areas are covered by other Cochrane Reviews (Canning 2015; Verheyden 2013). We acknowledge that some individuals with these (and other) health conditions may be included in studies of the general community.

Types of interventions

This review will include all trials of environmental interventions that measured falls in older people.

The descriptions of interventions used in individual trials will be examined and the intervention categorised according to the following primary categories.

1. Assistive technology or devices as a single strategy to reduce fall risk (such as personal mobility, body-worn aids, communication and sensory, self care aids).

2. Education/knowledge related to environmental fall risks as a sole intervention to reduce fall risk.

3. Home modifications as a single strategy or stand-alone intervention to improve independence, task performance, and safety (e.g. modifications to kitchen bench heights to assist task performance; removing shower hobs (e.g. sills) in bathrooms and other bathroom toilet modifications; installing ramps and rails).

4. Home fall hazard reduction as a single strategy or package of strategies to reduce fall risk (indoors or outdoors environmental adaptations such as non-slip strips on stairs, way-finding lighting at night, removing clutter in traffic ways; handrails and lighting at entrances; behavioural changes such as using a step ladder instead of climbing on chairs to reach high places or holding a rail when descending stairs).

Intervention scope, uptake, duration, intensity (comprehensive assessment of person and environment related to fall risk; priority setting with participant, follow-up), and additional information or support are expected to vary in the trials and will be noted and reported in our review.

For our main comparisons, we will include trials where the intervention was compared with 'usual care' (i.e. no change in usual activities) or a control intervention (attention control, i.e. an intervention that is not thought to reduce falls but provides attention, e.g. general health education or social visits). We plan the following comparisons.

1. Assistive technology (as a single component intervention) (e.g. footwear modifications, vision modifications) versus control.

2. Information/education (as a stand-alone intervention) versus control.

3. Home modifications (as a stand-alone intervention) to improve independence versus control.

4. Home fall hazard reduction interventions (as a single intervention or package of components) versus control.

Where appropriate, we will also compare interventions from the different categories, in particular where interventions are compared with information/education alone. We will select the least intensive or complex intervention for the control group, for example information/education where compared with home modifications.

We will also consider comparisons of high- versus low-intensity interventions and of different delivery personnel (e.g. occupational therapists versus non-specialist providers who do not have qualifications and training in person-environment fit).

Types of outcome measures

Primary outcomes

1. Rate of falls (number of falls; falls per person-year).

Secondary outcomes

1. Number of fallers (i.e. number of people experiencing one or more falls; risk of falling).

2. Number of people experiencing one of more fall-related fractures.

3. Number of people experiencing one or more falls that resulted in hospital admission.

4. Number of participants experiencing one or more falls that required medical attention.

5. Health-related quality of life (measured using a validated scale, e.g. EQ-5D (EQ-5D; Herdman 2011) or similar).

6. Number of participants experiencing one or more adverse events.

We have chosen the rate of falls as the single primary outcome for ease of interpretation of the results of the review. Furthermore, rate of falls is likely to be more sensitive to change than the proportion of fallers, especially in samples with high fall rates. As falls are count data, dichotomisation to falling versus not falling represents a loss of information, therefore many trials use rate of falls as the primary outcome and negative binomial regression to compare the rates between intervention and control groups, as recommended by Robertson 2005.

We will record and report intervention adherence data where available for use in the interpretation of trial and review findings.

We will extract health economic data (cost utilisation, cost benefit, and cost-effectiveness) where this information is available.

Timing of outcome measurement

We will assess outcomes at short-term (less than 18 months) and long-term (18 months or longer) follow-up. For studies with less than 18 months of follow-up, we will use the longest duration reported.

Search methods for identification of studies

Electronic searches

Our search will extend the searches performed up to February 2012 in Gillespie 2012. We will search the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (February 2012 to present), the Cochrane Central Register of Controlled Trials (CENTRAL) (Cochrane Register of Studies Online) (2012 Issue 3 to current issue), MEDLINE (March 2012 to present), Embase (March 2012 to present), CINAHL (Cumulative Index to Nursing and Allied Health Literature) (February 2012 to present), and OTseeker (Occupational Therapy Systematic Evaluation of Evidence) (to present), using tailored search strategies. We will not apply any language restrictions.

In MEDLINE, we will combine subject-specific search terms with the sensitivity- and precision-maximising version of the Cochrane Highly Sensitive Search Strategy for identifying randomised trials (Lefebvre 2011). The search strategies for CENTRAL, MEDLINE, Embase, and CINAHL are shown in Appendix 2.

We will also search the World Health Organization International Clinical Trials Registry Platform (WHO ICTRP) (apps.who.int/trialsearch/) and the US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (clinicaltrials.gov/) for ongoing and recently completed trials.

Searching other resources

We will check reference lists of other systematic reviews. We will also contact researchers in the field to identify ongoing and unpublished trials.

Data collection and analysis

Selection of studies

Two review authors will independently screen the titles and abstracts of the citations retrieved by the searches for relevance. After this initial assessment, we will obtain full-text copies of all potentially relevant studies. Two review authors will independently check the full papers for eligibility, resolving any disagreements by consensus and the input of a third review author. We will attempt to contact study authors where the eligibility of a study is unclear.

We will record the reasons for exclusion of studies obtained as full text. We summarise this process in a PRISMA flowchart. Where there are several reports of a study, we will attempt to obtain all reports.

Data extraction and management

Pairs of review authors (LC, SS, AP) will independently perform data extraction using a data extraction form based on the one used in Gillespie 2012. We will pilot the data extraction form using a representative sample of studies in order to identify any missing items or unclear coding instructions. Any disagreements will be resolved by consensus or third-party adjudication. Review authors will not be blinded to authors and sources. They will not assess their own trials.

We will use the standardised data extraction form to record the following items.

1. General information: review author's name, date of data extraction, study ID, first author of study, author's contact address (if available), citation of paper, and trial objectives.

2. Trial details: trial design, location, setting, sample size, inclusion and exclusion criteria, comparability of groups, length of follow-up, stratification, stopping rules, and funding source.

3. 'Risk of bias' assessment: sequence generation, allocation concealment, blinding (participants, personnel, outcome assessors), incomplete outcome data, selective outcome reporting, and other bias (recall bias).

4. Characteristics of participants: age, gender, ethnicity, and number randomised, analysed, lost to follow-up, and dropouts in each arm (with reasons).

5. Interventions: experimental and control interventions, timing of intervention, intensity of intervention/s, whether studies assessed adherence (compliance) with experimental and control interventions and associated data, who delivered the intervention, and additional co-interventions (such as motivational strategies). We will collect as much information as we can on control interventions, including assessing what 'usual care' comprised.

6. Outcomes measured: rate of falls, number of fallers, number of people experiencing one or more fall-related fractures, number of people who experienced one or more falls that resulted in hospital admission, number of participants who experience one or more falls that required medical attention, health related quality of life, and number of people experiencing one or more adverse events.

7. Other details: cost and cost-effectiveness information.

We will retrieve data from both full-text and abstract reports of studies, including those with multiple reports. Where information is insufficient, we will contact the study authors for additional details.

Assessment of risk of bias in included studies

Pairs of review authors (LC, AP, SS) will independently assess risk of bias using Cochrane's 'Risk of bias' tool (Higgins 2011). Any disagreements will be resolved by consensus or third-party adjudication (LC or CS).

As outlined in Appendix 3, we will assess the following domains: random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias, for falls and fractures separately), incomplete outcome data (attrition bias, for falls and fractures separately), and selective outcome reporting (reporting bias). We will also assess bias in the recall of falls due to unreliable methods of ascertainment (Hannan 2010). Specifically for trials using cluster randomisation, we will consider the risk of additional bias relating to recruitment, baseline imbalance, loss of clusters, incorrect analysis, and comparability with individually randomised trials, as described in Chapter 16 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

We will rate risk of bias as either low, high, or unclear for each domain.

Measures of treatment effect

We will report the treatment effects for rate of falls, fractures, and falls requiring medical attention as a rate ratio (RaR) with 95% confidence intervals (CIs). For number of fallers, number of participants sustaining fall-related fractures, and number of participants experiencing falls that required medical attention, we will report risk ratios (RR) and 95% CIs.

The rate of falls is the total number of falls per unit of person-time that falls were monitored (e.g. falls per person-year). The RaR compares the rate of falls in any two groups during each trial. We will use an RaR (e.g. incidence RaR or hazard ratio for all falls) with a 95% CI if these were reported in the paper. If both adjusted and unadjusted RaRs were reported, we will use the unadjusted estimate unless the adjustment was for clustering. If an RaR was not reported but appropriate raw data are available, we will use an Excel spreadsheet (2018) to calculate an RaR and 95% CI. We will use the reported rate of falls (falls per person-year) in each group and the total number of falls for participants contributing data, or we will calculate the rate of falls in each group from the total number of falls and the actual total length of time falls were monitored (person-years) for participants contributing data. In cases where data were only available for people who had completed the study, or where the trial authors reported no losses to follow-up, we will assume that these participants had been followed up for the maximum possible period.

For number of fallers, a dichotomous outcome, we will use the RR as the treatment effect. The RR compares the number of people who fell once or more (fallers) between groups. We will use a reported estimate of risk (hazard ratio for first fall, risk ratio (relative risk), or odds ratio) and 95% CI if available. If both adjusted and

unadjusted estimates were reported, we will use the unadjusted estimate, unless the adjustment was for clustering. If an odds ratio was reported, or an effect estimate and 95% CI confidence interval was not reported, and appropriate data were available, we will calculate an RR and 95% CI using the 'csi' command in Stata (StataCorp 2017). For the calculations we will use the number of participants contributing data in each group if this is known; if this is not reported we will use the number randomised to each group. We will use the same approach for the number of people sustaining fractures, the number of people experiencing falls requiring medical attention, and the number of people experiencing adverse events.

For continuous outcomes (health-related quality of life), we will present the mean difference (MD) with 95% CIs where the same outcome measure was used, or standardised mean difference (SMD) with 95% CIs for outcomes measured using different scales. We will only use results based on change scores if final values are unavailable.

Unit of analysis issues

For trials that are cluster randomised (e.g. by medical practice), we will perform adjustments for clustering as described in Higgins 2011 if this was not done in the published report. We will use an intraclass correlation coefficient (ICC) of 0.01 as reported in Smeeth 2002. We will ignore the possibility of a clustering effect in trials randomising by household.

For trials with multiple arms, we will include multiple pair-wise comparisons (intervention versus control) in analyses, but to avoid the same group of participants being included twice, we will 'split' the control group by distributing the number of control group participants to each analysis in proportion to the number of participants in each intervention group.

We will be alert to the unit of analysis issues relating to outcome reporting at different follow-up times and the presentation of outcomes, such as adverse events, by the number of outcomes rather than participants with these outcomes.

Dealing with missing data

It is inevitable that data will be missing for some participants in studies of older people given the increased risk of ill health, institutionalisation, and death. We will attempt to contact study investigators for any key missing or unclear data or information on their trial. We will conduct sensitivity analysis to explore the effects of missing data (incomplete outcome data) on the treatment effect.

If a study does not report SDs for continuous outcomes, we will calculate these from standard errors, CIs, or exact probability (P) values where possible. We will not impute missing SDs.

Assessment of heterogeneity

The decision about whether or not to combine the results of individual studies will depend on an assessment of clinical and methodological heterogeneity. If we consider studies sufficiently homogeneous in their study design, we will carry out meta-analyses and assess the statistical heterogeneity. We will assess statistical heterogeneity of treatment effects between trials by visual inspection of the graphs, Chi² test with a significance level at P < 0.10, and the I² statistic. We will base our interpretation of the I² results on that suggested by Higgins 2011: 0% to 40% might not be important; 30% to 60% may represent moderate heterogeneity; 50% to 90% may represent substantial heterogeneity; and 75% to 100% may represent very substantial ('considerable') heterogeneity.

Assessment of reporting biases

To explore the possibility of publication and other reporting biases, we will construct funnel plots for analyses that contain more than 10 data points.

Data synthesis

We will group similar environmental interventions for analysis using the classification system proposed in this protocol, which has built upon and broadened the scope of the earlier ProFaNE taxonomy (Lamb 2005). For example, we will only group the assistive technology interventions if the technology or devices are similar.

When considered appropriate, we will pool the results of comparable studies using both fixed-effect and random-effects models. The choice of the model to report will be guided by careful consideration of the extent of heterogeneity and whether it can be explained, in addition to other factors such as the number and size of included studies. We will use 95% CIs throughout. We will consider not pooling data where there is considerable heterogeneity (I² ≥ 75%) that cannot be explained by the diversity of methodological or clinical features among trials. Where pooling data is inappropriate, we will still present trial data in the analyses or tables for illustrative purposes and will report these in the text. When considered appropriate, we will pool data using the generic inverse variance method in Review Manager 5 (RevMan 5.3). This method enables pooling of the adjusted and unadjusted treatment effect estimates (rate ratios or risk ratios) reported in the individual studies or that can be calculated from data presented in the published article (see Measures of treatment effect). The generic inverse variance option in Review Manager 5 requires entering the natural logarithm of the rate ratio or risk ratio and its standard error for each trial; we will calculate these in an Excel spreadsheet (2018).

Subgroup analysis and investigation of heterogeneity

Where sufficient data are available, within all outcomes and categories of environmental interventions as outlined, we will explore heterogeneity by carrying out the following prespecified subgroup analyses.

1. Higher versus lower falls risk at enrolment (i.e. comparing trials with participants selected for inclusion based on history of falling, recent hospitalisation, or other specific risk factors for falling, versus unselected participants).

2. For the home fall hazard intervention: high versus low intensity of intervention (e.g. intensity would be where interventions meet 75% of the identified criteria described in the Description of the intervention section and as reported by Clemson 2008).

3. Delivery by people with different qualifications (e.g. for the home fall hazard reduction intervention and home modification trials that used an occupational therapist, ergotherapist, or equivalent versus those trials that were delivered by a health care worker who did not possess specific training in evaluating person-environment fit).

We will use the test for subgroup differences available in Review Manager 5 to determine whether there is evidence for a difference in treatment effect between subgroups (RevMan 5.3).

Sensitivity analysis

Where possible, we will assess the robustness of our findings by conducting sensitivity analyses.
We will examine the effects of the following.

1. Inclusion of trials at high or unclear risk of selection bias due to inadequate concealment of allocation.

2. Inclusion of trials at high or unclear risk of detection bias due to inadequate blinding of outcome assessors.

3. Inclusion of trials at high or unclear risk of attrition bias due to incomplete outcome data.

4. The effect of time on the impact of the intervention (i.e. comparing differences in treatment effect over time - earlier trials versus later trials).

5. The choice of statistical model for pooling (fixed-effect versus random-effects).

6. The inclusion of cluster-randomised trials.

Assessing the quality of the evidence and 'Summary of findings' tables

We will use the GRADE approach to assess the quality of evidence as it relates to the primary and secondary outcomes listed in the Types of outcome measures section (Schünemann 2011). The quality rating 'high' is reserved for a body of evidence based on randomised controlled trials. We may downgrade the quality rating to 'moderate', 'low', or 'very low' depending on the presence and extent of five factors: study limitations, inconsistency of effect, imprecision, indirectness, and publication bias.

Where evidence is sufficient, we will prepare 'Summary of findings' tables for the primary outcome and secondary outcomes for individual comparisons described in the Types of interventions section.

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* *Indicates the major publication for the study*

A P P E N D I C E S

Appendix 1. Mapping of ProFaNE fall prevention classification taxonomy (Lamb 2007) to the Cochrane Environmental Intervention Descriptors

ProFaNE classification	Assistive technology (ISO9999, 2002[a])	Knowledge/education intervention	_	Home hazard management (C300)
Cochrane intervention classification	Assistive technology (as a single strategy) (WHO, ISO9999, 2016[a])	Information/ education on environmental fall risks (as a single strategy)	Home modifications (as a single strategy)	Home fall hazard reduction (may be single or package of strategies)
Main intervention aim	Reduce falls	Reduce falls	Improve task performance, independence, and accessibility for people with disability (activity limitations)	Reduce falls and environmental and behavioural fall risk
ProFaNE taxonomy descriptors	Illustrative examples from classification used in review			
Assessment				

(*Continued*)

Environment assessment (dwelling unit) **C207**	–	e.g. self completed checklist as a single strategy	e.g. performance-based functional assessments/ assessment of environmental barriers to function	e.g. formal assessment of fall hazards in and about the home; environmental risk assessment taking into account individual capacity
Environment assessment (public) **C208**	–	–	–	Extension to public places is possible.
Environment/assistive technology[a]				
Furnishings and adaptations to homes **D700**	–	–	e.g. features of the house designed to assist a disabled person to function independently such as grab rails, stair lifts, task lighting, remove shower recess hob	e.g. features of the home that can be adapted to reduce fall risk such as lighting for safe mobility, grab rails, safety equipment such as non-slip materials for floors and stairs
Aids for personal mobility **D710**	e.g. mobility aids	–	e.g. mobility aids, wheelchairs, lifting aids	e.g. mobility aids
Aids for communication, information, and signalling (optical) **D720**	e.g. eyeglasses to aid or improve vision	–	–	–
Aids for communication, information, and signalling (hearing) **D721**	e.g. hearing aids to amplify sound	–	–	–
Aids for protection - alarm systems **D723**	e.g. falls monitor (personally worn devices)	–	–	–
Body-worn aids for personal care and protection: protective aids **D730**	e.g. hip protectors[b]	–	–	–
Body-worn aids for personal care and protection: clothes and shoes **D731**	e.g. antislip devices for shoes; orthotic footwear	–		e.g. safe footwear; clothing (such as clothing that is not trippable when climbing stairs)

Other environmental interventions				
Behavioural adaptations (ProFaNE - see under psychological)	-	-	-	Behavioural safety strategies to reduce fall risk (e.g. activity avoidance, cognitive adaptations, practical strategies)
Self management (Pro-FaNE - see B600)	-	-	-	e.g. self-risk evaluation (jointly with therapist) ; strategy instruction to prevent future falls
Environmental - social				
Caregiver training **D804**	-	-	-	e.g. target important aspects of fall prevention and safety at home
Knowledge				
e.g. pamphlets, information, booklets, videos, lectures **D900**	-	Information/education about reducing environmental fall risks in the home as a stand-alone intervention	-	-
Postintervention follow-up				
Others **D999**	-	-	Follow up to ensure modifications have been installed	Follow through to ensure recommendations are completed and appropriate and that older person perceives they have reduced falls risk

[a] These ProFaNE intervention categories were based on the 2002 International Standard ISO 9999 'Technical aids for persons with disabilities - classification and terminology'. This is now updated and published as WHO Assistive products for persons with disability - 2016 WHO International Standard ISO 9999 'Classification and terminology for persons with disability' 6th edition.
[b] Hip protectors as a sole intervention are covered in a separate Cochrane Review, that includes rate of falls among the types of outcomes (Santesso 2014).

Appendix 2. Search strategies

CENTRAL (CRS Online)

#1 MESH DESCRIPTOR Accidental Falls
#2 (falls or faller*):TI,AB,KY
#3 #1 OR #2
#4 MESH DESCRIPTOR Aged EXPLODE ALL TREES
#5 (senior* or elder* or old* or aged or ag?ing or postmenopausal or community dwelling):TI,AB,KY
#6 #4 OR #5
#7 #3 AND #6

MEDLINE (Ovid Interface)

1 Accidental Falls/
2 (falls or faller$1).tw.
3 or/1-2
4 exp Aged/
5 (senior*1 or elder* or old* or aged or ag?ing or postmenopausal or community dwelling).tw.
6 or/4-5
7 3 and 6
8 Randomized controlled trial.pt.
9 Controlled clinical trial.pt.
10 randomized.ab.
11 placebo.ab.
12 Clinical trials as topic/
13 randomly.ab.
14 trial.ti.
15 8 or 9 or 10 or 11 or 12 or 13 or 14
16 exp Animals/ not Humans/
17 15 not 16
19 7 and 17

Embase (Ovid Interface)

1 Falling/
2 (falls or fallers).tw.
3 or/1-2
4 exp Aged/
5 (senior*1 or elder* or old* or aged or ag?ing or postmenopausal or community dwelling).tw.
6 or/4-5
7 3 and 6
8 exp Randomized Controlled Trial/ or exp Single Blind Procedure/ or exp Double Blind Procedure/ or Crossover Procedure/
9 (random* or RCT or placebo or allocat* or crossover* or 'cross over' or trial or (doubl* adj1 blind*) or (singl* adj1 blind*)).ti,ab.
10 8 or 9
11 (exp Animal/ or animal.hw. or Nonhuman/) not (exp Human/ or Human cell/ or (human or humans).ti.)
12 10 not 11
13 7 and 12

CINAHL (EBSCO)

S1 (MH "Accidental Falls")
S2 TI (falls or faller*) OR AB (falls or faller*)

S3 S1 OR S2
S4 (MH "Aged+")
S5 TI (senior* or elder* or old* or aged or ag?ing or postmenopausal or community dwelling) OR AB (senior* or elder* or old* or aged or ag?ing or postmenopausal or community dwelling)
S6 S4 OR S5
S7 S3 AND S6
S8 PT Clinical Trial
S9 (MH "Clinical Trials+")
S10 TI clinical trial* OR AB clinical trial*
S11 TI ((single blind* or double blind*)) OR AB ((single blind* or double blind*))
S12 TI random* OR AB random*
S13 S8 OR S9 OR S10 OR S11 OR S12
S14 S7 AND S13

OTseeker

Advanced search option selected
Abstract and Title: Fall
Age group: gerontology

Appendix 3. 'Risk of bias' assessment tool*

Domain	Criteria for judging risk of bias
Random sequence generation relating to selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence	• Judgement of 'low risk' if the trial authors described a random component in the sequence generation, e.g. referring to a random number table; using a computer random number generator; coin tossing; shuffling cards or envelopes; throwing dice; drawing of lots; minimisation. • Judgement of 'high risk' if the trial used a systematic non-random method, e.g. date of admission; odd or even date of birth; case record number; clinician judgement; participant preference; patient risk factor score or test results; availability of intervention. • Judgement of 'unclear risk' if there is insufficient information about the sequence generation process to permit judgement of 'low risk' or 'high risk'.
Allocation concealment relating to selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment	• Judgement of 'low risk' in studies using: ○ individual randomisation if the trial described allocation concealment as by central allocation (telephone, internet-based, or pharmacy-controlled randomisation); sequentially numbered, identical drug containers; sequentially numbered, opaque, sealed envelopes; ○ cluster randomisation if allocation of all cluster units performed at the start of the study and individual participant recruitment was completed prior to assignment of the cluster, and the same participants were followed up over time or

	individual participants were recruited after cluster assignment, but recruitment was carried out by a person unaware of group allocation and participant characteristics (e.g. fall history), or individual participants in intervention and control arms were invited by mail questionnaire with identical information. - Judgement of 'high risk' in studies using: - individual randomisation if investigators enrolling participants could possibly have foreseen assignments thus introducing selection bias, e.g. using an open random allocation schedule (e.g. a list of random numbers); assignment envelopes unsealed, non-opaque, or not sequentially numbered; alternation or rotation; date of birth; case record number; or any other explicitly unconcealed procedure; - cluster randomisation if individual participant recruitment was undertaken after group allocation by a person who was unblinded and may have had knowledge of participant characteristics. - Judgement of 'unclear risk' if insufficient information to permit judgement of 'low risk' or 'high risk'. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definitive judgement, e.g. if the use of assignment envelopes is described, but it is unclear whether envelopes were sequentially numbered, opaque, and sealed.
Blinding of participants and personnel relating to performance bias due to knowledge of the allocated interventions by participants and personnel carrying out the interventions	- Judgement of 'low risk' if blinding of participants and personnel implementing the interventions was ensured and it is unlikely that the blinding could have been broken, or blinding was not done but the review authors judge that the outcomes (falls and fractures) are unlikely to be influenced by lack of blinding. - Judgement of 'high risk' if participants or intervention delivery personnel, or both were not blinded to group allocation (e.g. exercise intervention), and the outcomes (falls and fractures) are likely to be influenced by lack of blinding. - Judgement of 'unclear risk' if there is insufficient information to permit a judgement of 'low risk' or 'high risk'.
Blinding of outcome assessment relating to detection bias due to knowledge of the allocated interventions by outcome assessors	- Falls, fallers: - judgement of 'low risk' if outcomes were recorded/ confirmed in all allocated groups using the same method and the personnel recording/confirming outcomes were blind to group allocation; - judgement of 'high risk' if outcomes were not recorded/confirmed in all allocated groups using the same method or the personnel recording/confirming outcomes were NOT blind to group allocation; - judgement of 'unclear' if there is insufficient information to permit a judgement of 'low risk' or 'high risk'.

	- Fractures:
	    ○ judgement of 'low risk' if fractures were recorded/ confirmed in all allocated groups using the same method, and fractures were confirmed by the results of radiological examination or from primary care case records and the personnel recording/confirming fractures were blind to group allocation;
	    ○ judgement of 'high risk' if fractures were not recorded/ confirmed in all allocated groups using the same method, or the only evidence for fractures was from self reports from participants or carers;
	    ○ judgement of 'unclear risk' if there is insufficient information to permit a judgement of 'low risk' or 'high risk'.

Incomplete outcome data relating to attrition bias due to amount, nature, or handling of incomplete outcome data	- Judgement of 'low risk' if there are no missing outcome data, or less than 20% of outcome data are missing and losses are balanced in numbers across intervention groups with similar reasons for missing data across groups, or missing data have been imputed using appropriate methods. - Judgement of 'high risk' if greater than 20% of outcome data are missing, or reasons for missing outcome data are likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups, or 'as-treated' analysis done with substantial departure of the intervention received from that assigned at randomisation or potentially inappropriate application of simple imputation. - Judgement of 'unclear risk' if there is insufficient information to permit a judgement of 'low risk' or 'high risk'.
Selective outcome reporting relating to bias due to the selective reporting or non-reporting of findings	- Judgement of 'low risk' if the study protocol is available and all prespecified study outcomes are reported in the prespecified way, or the study protocol is unavailable but it is clear that the published report includes all expected outcomes. - Judgement of 'high risk' if not all prespecified study outcomes are reported, or one or more primary outcomes are reported in ways that were not prespecified, or one or more outcomes are reported incompletely or the study fails to include results for a key outcome that would be expected to have been reported. - Judgement of 'unclear risk' if there is insufficient information to permit a judgement of 'low risk' or 'high risk'.
Method of ascertaining falls relating to bias in the recall of falls due to unreliable methods of ascertainment	- Judgement of 'low risk' if the study used some form of concurrent collection of data about falling, e.g. participants were given postcards to fill in daily and mail back monthly, calendar to mark monthly, or, more frequently, follow-up by the researchers. - Judgement of 'high risk' if ascertainment relied on participant recall at longer intervals than one month during the study or at its conclusion. - Judgement of 'unclear risk' if there was retrospective recall

	over a short period only, or if the trial authors did not describe details of ascertainment, i.e. insufficient information was provided to permit a judgement of 'low risk' or 'high risk'.
Cluster-randomised trials relating to bias due to factors particular to cluster-randomised trials	• Judgement of 'low risk' if the study predominantly had the following characteristics: ○ individuals were recruited to the trial prior to randomisation of the clusters; ○ baseline comparability of clusters was reported or there was statistical adjustment for baseline characteristics; ○ no loss of clusters or missing outcomes for individuals within specific clusters; ○ clustering is accounted for in the analyses; ○ results are comparable with individually randomised trials. • Judgement of 'high risk' if the study predominantly had the following characteristics: ○ individuals were recruited to the trial after randomisation of the clusters; ○ baseline comparability of clusters was not reported, and there was no statistical adjustment for baseline characteristics; ○ loss of entire clusters or missing outcomes for individuals within clusters; ○ no accounting for clustering in analyses; ○ results not comparable with individually randomised trials. • Judgement of 'unclear risk' if there is insufficient information to permit a judgement of 'low risk' or 'high risk'.

*We adapted this from Table 8.5.a 'The Cochrane Collaboration's tool for assessing risk of bias' and Table 8.5.d 'Criteria for judging risk of bias in the 'Risk of bias' assessment tool' (Higgins 2011).

CONTRIBUTIONS OF AUTHORS

Lindy Clemson: contributed to writing the protocol and will act as guarantor of the review

Susan Stark: contributed to writing the protocol

Alison C Pighills: contributed to writing the protocol

David J Torgerson: commented on the protocol draft

Catherine Sherrington: contributed to writing the protocol

Sarah E Lamb: contributed to writing the protocol

Contributions of the editorial base

Helen Handoll (Co-ordinating Editor): edited the protocol; advised on methodology and protocol content; and approved the final version for publication.
Joanne Elliott and Lindsey Elstub (Managing Editors): coordinated the editorial process; advised on content; and edited the protocol.
Joanne Elliott (Information Specialist): designed the search strategy and edited the search methods section.
Zipporah Iheozor-Ejiofor (Methodologist): advised on methodology.

DECLARATIONS OF INTEREST

Lindy Clemson developed an intervention that has been tested in two previous trials.

Susan Stark has no known conflicts of interest.

Alison C Pighills previously ran a trial of an environmental intervention to reduce falls; she will not review her own trial.

David J Torgerson is currently running a trial of environmental interventions and is an author on a previous trial; he will not review his own trials.

Catherine Sherrington has no known conflicts of interest.

Sarah E Lamb has no known conflicts of interest.

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